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Clinicon CORPORATION
5825 AVENIDA ENCINAS • CARLSBAD, CA 92008

FEB 1 1 2002

510(k) Summary

Submitter:	Clinicon Corporation 5825 Avenida Encinas Carlsbad, CA 92008
Contact person:	Sean M. Curry 16787 Bernardo Center Drive, Suite A San Diego, CA 92128
Phone:	(858) 675-8200
FAX:	(858) 675-8201
Proprietary name:	Clinicon Universal WaveGuide Handpiece and Fiber Tips
Common name:	CO_2 Laser Powered Surgical Instrument
Classification:	878.4810
Product Code:	GEX
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.

Substantial equivalence claimed to:

K903079, Luxar's Endoguide ®, Microguide ™, Flexiguide™
K992472, Clinicon's SureGuide CO2 Laser Beam Delivery System

Description:

The Universal WaveGuide Handpiece comes in two designs, one that accepts 1.5 mm O.D. size fiber tips and one that accepts 2.5 mm O.D. size fiber tips. The 1.5 mm handpiece is used with the Free Beam and Flexible fiber tips. The 2.5 mm handpiece is used with the rigid fiber tips.

The collet component determines the O.D. size fibers that can be inserted into the handpiece. The nozzle and tip lock collet secures the fiber and prevents twisting of the fiber tip. The hand piece is attached to the Clinicon WaveGuide Platform by the FSMA connector at the distal end of the waveguide.

The Fiber Tips are made of the same proprietary waveguide fiber as the Clinicon WaveGuide Platform, described in the premarket notification, K992472, SUREGUIDE CO2 Laser Beam Delivery System.

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The waveguide fiber is inserted into a straight or curved stainless steel sheath for the 2.5 mm O.D. rigid fiber tips or into a Teflon tube for the 1.5 mm O.D. flexible fiber tips.

The fiber tips, both rigid and flexible are of various lengths for use in various surgical procedures. The rigid fiber tips are also of various degrees of curvature and certain tips may have a contact probe tip cover made of Teflon.

The fiber tips are disposable, single-use devices, and both the rigid and flexible fiber tips have a section of colored polyethylene at the distal end of the fiber cable that acts as a depth gauge to assure the fiber is completely seated in the handpiece. The colored polyethylene also acts as a sterilizer indicator that will render the tips unusable if they are re-sterilized by distorting the polyethylene and preventing the fiber from being inserted into the handpiece.

Intended use:

The Clinicon Universal WaveGuide Handpiece and Fiber Tips are intended to be used to deliver carbon dioxide laser energy for the incision, excision, vaporization, ablation, coagulation or cauterization of soft tissue.

Summary of technological characteristics:

The Clinicon Universal WaveGuide Handpieces have the same technological characteristics as the Luxar handpieces used with Luxar medical fiber tips. The Clinicon Fiber Tips have the same technological characteristics as the Clinicon Sureguide CO2 Laser Beam Delivery System, now marketed as the Clinicon Waveguide Platform.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Clinicon Corporation
c/o Mr. Sean M. Curry
Certified Software Solutions, Inc.
16787 Bernardo Center Drive, Suite A
San Diego, California 92128

Re: K014048
Trade Name: Clinicon Universal Waveguide Handpiece and Fiber Tips
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: December 4, 2001
Received: December 7, 2001

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014048

Device Name:

Indications for Use:

The Clinicon UHP/disposable tip is/are indicated for use in general and plastic surgery, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology, and urology procedures for incision, excision, vaporization, ablation, coagulation, cauterization of soft tissue.

The Clinicon UHP/disposable tip indications are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014048

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)